FEB - 6 2014

510(k) Summary
Fuse 1C Colonoscopy System

1. Company Identification

Manufacturer:
EndoChoice Innovation Center, Ltd. (Formerly PeerMedical, Ltd.)
2 Hatochen St.
Business Industrial Park North
Caesarea, ISRAEL 38900
Establishment Registration: Active Status, awaiting establishment registration number

Owner/Operator:
EndoChoice, Inc.
11810 Wills Road Suite 100
Alpharetta, GA 30009
Owner/Operator Number: 10028290
Establishment Registration: 300759133

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager
EndoChoice, Inc.

3. Device Name

Trade name:	Fuse 1C Colonoscopy System
Common/Usual Name:	Colonoscope, Video
Classification name:	Endoscope and Accessories

4. Device Classification

Common Name:	Colonoscope and accessories, flexible / rigid
Classification:	Colonoscope and accessories, 21CFR 876.1500
Product Code:	FDF
Committee:	Gastroenterology/Urology

5. Intended Use

The Fuse 1C System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients.

The Fuse 1C System consists of camera heads, endoscopes, video system, light source and other ancillary equipment

6. Device Description

The Fuse™ 1C Colonoscopy System is a GI platform for diagnostic visualization and therapeutic intervention of the lower digestive tract. The system enables physicians to view high resolution wide field of view of up to 300°. The Fuse 1C is a modification of the legally marketed (K130718) PeerScope system Model H (the predicate device). The device has been modified to include a water bottle, cap, and tubing that are specified for use only with the Fuse1C.

The Fuse 1C Colonoscopy System consists of the following components:

- The Fuse 1C colonoscope is a flexible, adult size video colonoscope labeled for repeatable clinical usage within health care facilities. The colonoscope design and materials have not been modified, aside from a change in market name.
- The main control unit (FuseBox™) performs image processing and relays video signals from the video colonoscope to external display monitors. The FuseBox also offers pneumatic controls and interfaces with various external accessories.
- Ancillary components and accessories for use in reprocessing and irrigation. A change in water bottle/cap/tubing is the difference between the predicate device and the Fuse 1C device submitted herein for review.

7. Substantial Equivalence

7.1. Predicate devices

The Fuse 1C System is a modification of, and is substantially equivalent to, the PeerScope System Model H (K130718). The intended use, design, materials and labeling are all substantially equivalent.

7.2. Intended Use

The Fuse 1C System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients.

The Fuse 1C System consists of camera heads, endoscopes, video system, light source and other ancillary equipment

The intended use is identical to the predicate device PeerScope System Model H.

7.3. Technical Characteristics

The Fuse 1C system is technically identical to the predicate PeerScope System Model H, with the exception of a change in specified accessory.

This is not a change in technology. The change does not impact indications for use. Validation of the modification did not raise new questions of safety and effectiveness.

7.4. Performance Characteristics

The system is now specified for use with the SCT-468 Reusable Water Bottle, Cap, and Tubing Set and SCT-469 Reusable Water Bottle, Cap, and Tubing with CO_2 Set. These accessorial sub-components are included with the Fuse 1C system.

Summary of Differences		
Category	**Predicate Device (PeerScope system Model B K130718)**	**Subject Device (Fuse 1C Colonoscope)**
Colonoscope Model	PeerScope CS	Fuse 1C (trade name change)
Water-feed system	Specified third party water bottle, cap, and tubing pressurized by pump	EndoChoice re-usable water bottle and water bottle cap pressurized by pump. Accessory is specified for use with Fuse endoscope system only.

The steps for operator use of each of the devices are identical, except that a specified accessory water bottle, cap and tubing set are now identified in instructions. Instructions for use of the accessory are now also included in a separate insert.

8. Non-clinical testing

Non-clinical testing has been performed on the device. Specifically, the following has been completed on the accessory water bottle, cap, and tubing:

- Benchtop functional performance testing
- Laboratory validation testing of the cleaning instructions
- Laboratory validation testing of the high-level disinfection instructions
- Laboratory validation testing of sterilization instructions
- Biocompatibility testing in conformance with ISO 10993-1.

All test results passed, demonstrating that the device is safe and effective in comparison with the predicate device.

9. Conclusion

The modification of the Fuse 1C is substantially equivalent to the predicate device PeerScope System Model H listed above. It is the same or equivalent in terms of design, intended use, materials, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

EndoChoice, Inc.
Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K132839
Trade/Device Name: Fuse 1C Colonoscopy System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: December 31, 2013
Received: January 3, 2014

Dear Daniel Hoefer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132839

Device Name
Fuse 1C Colonoscopy System

Indications for Use *(Describe)*
The Fuse 1C Colonoscopy System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The Fuse 1C Colonoscopy System is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients.

The Fuse 1C Colonoscopy System consists of camera heads, endoscopes, video system, light source and other ancillary equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.02.06 11:13:40 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."